NDA 50-622/S-014

Lederle Laboratories
Attention: Roberta R. Acchione
Associate Director, U.S. Regulatory Affairs
170 North Radnor-Chester Rd.
St. Davids, PA 19087

Dear Ms. Acchione:

Please refer to your supplemental new drug application dated August 9, 1999, received August 12, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Suprax® (cefixime) Oral Suspension. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provides for the addition of the phrase, "Use immediately upon reconstituting with water" to the sample container label of the drug product.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The Final Printed Labeling (FPL) must be identical to the enclosed labeling (text for the package insert and immediate container and carton labels submitted August 9, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry entitled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-622/S-014". Approval of this submission by FDA is not required before labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we

request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-002
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mr. R. Grant Hills, Project Manager, at (301) 827-2125.

Sincerely,

Janice M. Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research